IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9045

Bartle, J. April 12, 2013

Robert A. Miller ("Mr. Miller" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Sheila R. Miller, Mr. Miller's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Mary K. Richards, M.D., F.A.C.C. Based on an echocardiogram dated December 10, 2002, Dr. Richards attested in Part II of Mr. Miller's Green Form that claimant suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[4]

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3. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Richards also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $486,424.[5]

In the report of claimant's echocardiogram, Dr. Richards stated that claimant had "moderate mitral regurgitation qualifying at 24% regurgitant jet under the strict criteria of Singh." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Donna M. Polk, M.D., M.P.H., one of its auditing cardiologists. In audit, Dr. Polk concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because his echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Polk stated, "The area traced for the [mitral regurgitant] jet is not seen in real time. In all views the [mitral regurgitation] is mild and is less than 20% of

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5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

the left atrial area."

Based on the attesting physician's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Mr. Miller's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that there was a reasonable medical basis for his claim because his December 10, 2002 and August 10, 2005 echocardiograms, which were performed by a doctor who participated in the Trust's Screening Program,[7] demonstrated moderate mitral regurgitation. In addition, Mr. Miller maintained that he did not have heart problems until after he ingested Diet Drugs.[8]

The Trust then issued a final post-audit determination,

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Miller's claim.

7. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

8. Mr. Miller also takes exception to the Trust's processing of his claim and the organization of the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue. We find no evidence that the Trust improperly mishandled Mr. Miller's claim or that the organization of the Green Form affected the processing of his claim.

again denying Mr. Miller's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Miller's claim should be paid. On August 2, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6455 (Aug. 2, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 6, 2006, and claimant submitted a sur-reply on March 23, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Miller submitted a letter from Dr. Richards. She stated, in pertinent part:

> I ascertain that they believe my measurements were based on still frame instead of real time images, which is not true. The measurements and the jet were taken in real time images and loops, all of which were reviewed by me in real time, and pictures of still frames were submitted in an effort to justify the measurements and jet percentages. I still stand by the Green Form submission, and that Mr. Miller has moderate mitral regurgitation by [echocardiogram].

> It is suggested that copying images and copied studies sometimes are altered from the original studies due to the process of copying the tapes.
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> Even if he has mild mitral regurgitation, that does not change the fact that Mr. Miller had no evidence of valvular abnormality and problems with his heart until after he took the medication Redux, Fen-Phen and Pondimin for one year. He also has a normal mitral valve with no prolapse or stenosis seen, but it does leak and this is [a] complication that is being linked to these diet drugs.

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for his claim because the statement of Dr. Richards is conclusory and inconsistent with Dr. Polk's findings at audit. In addition, the Trust contends that the issue of what caused Mr. Miller's mitral regurgitation is irrelevant to his claim for Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Miller had moderate mitral regurgitation. Specifically, Dr. Vigilante observed:

> I reviewed the four tapes of echocardiograms that accompanied the Special Master Record. The first tape was a copy of the study performed on December 10, 2002. . . . All of the usual echocardiographic views were obtained. However, the study was not performed in accordance with the usual standards of care. The Nyquist limit was set too low at 46 cm per second at a depth of 19 cm in the parasternal long-axis view and 46 cm per second at a depth of 23 cm in the

apical views. There was significantly increased color gain. This resulted in color artifact with inappropriate demonstration of low velocity, non-mitral regurgitant flow as well as back flow.

. . . . Visually, no mitral regurgitation was seen in the parasternal long-axis view and trace to mild mitral regurgitation was suggested on the apical views. I digitized those cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was best evaluated. I then digitally traced and calculated the RJA and LAA. In spite of an inappropriately low Nyquist limit and increased color gain, I was able to planimeter the RJA in the mid portion of systole. The largest representative RJA was 2.2 cm2 in the apical four chamber view. The LAA was 23.7 cm2. Therefore, the largest representative RJA/LAA ratio was 9%. The RJA/LAA ratio never came close to approaching 20%. The mitral regurgitant jet was even less impressive in the apical two chamber view. The largest representative RJA was less than 2.0 cm2 in this view. The sonographer demonstrated a supposed RJA of 3.94 cm2 and LAA of 16.68 cm2. The supposed RJA was not representative of mitral regurgitation and was low velocity and non-mitral regurgitant flow. The supposed LAA was measured in the same frame as the supposed RJA. This was an off axis view of the LAA and would not be consistent with left atrial enlargement. The correct LAA was 23.7 cm2. The incorrect sonographer determined RJA and LAA measurements were the same measurements as documented in Dr. Richards' report.

. . . .

I reviewed the second tape. This was an identical copy of the December 10, 2002 echocardiogram.

I reviewed the third tape. This was a copy of the August 10, 2005 study. . . . The

> usual echocardiographic views were obtained. However, this study was not performed in accordance with the usual standards of care. There was an inappropriately low Nyquist limit of 46 cm per second at a depth of 19 cm in the parasternal long-axis view and a Nyquist limit of 46 cm per second at a depth of 23 cm in the apical views. There was markedly high and excessive color gain with color artifact noted even outside the heart. There was inappropriate demonstration of low velocity, non-mitral regurgitant flow.
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> . . . . I was unable to determine the presence or absence of mitral regurgitation on this study due to the inappropriately low Nyquist limit and markedly increased color gain. I digitized those cardiac cycles in the apical four and two chamber views. The RJA could not be determined due to the inappropriate performance of the study. I digitally traced the LAA. The LAA in this study was 24.0 cm2. There was no evidence of moderate mitral regurgitation on this study. The sonographer demonstrated a supposed RJA of 5.92 cm2 and an LAA measurement of 15.25 cm2. The supposed RJA determination was artifact and not mitral regurgitation. The LAA determination was made in an off axis view of the left atrium in the same frame that the supposed RJA of 5.92 cm2 was determined. The correct LAA was 24.0 cm2.
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> . . . .
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> I reviewed the fourth echocardiogram tape. This was a copy of the August 10, 2005 echocardiogram with poor tracking. This was a below quality copy.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Contrary to claimant's contention, the letter from Dr. Richards does not establish a reasonable medical basis for her Green Form representation that

claimant had moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26.

Here, Dr. Polk determined, "The area traced for the [mitral regurgitant] jet is not seen in real time. In all views the [mitral regurgitation] is mild and is less than 20% of the left atrial area." Although Dr. Richards responded that the measurements were taken in real time and that she reviewed all the frames and loops, Dr. Vigilante reviewed claimant's echocardiograms and determined that they demonstrated only mild mitral regurgitation.

Dr. Vigilante also concluded that these echocardiograms were not performed in accordance with the proper standards of care. In particular, with respect to the December 10, 2002 echocardiogram, Dr. Vigilante observed that the supposed RJA measured by the attesting physician was not representative of mitral regurgitation and included low velocity and non-mitral regurgitant flow. With respect to the August 10, 2005 echocardiogram, Dr. Vigilante determined that the supposed RJA measured by Dr. Richards was artifact and not mitral regurgitation.[10] Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Moreover, we reject claimant's assertion that he is entitled to Matrix Benefits because the echocardiogram that forms the basis of his claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited

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10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the

Settlement Agreement in this fashion.

Finally, Mr. Miller's assertion that he is entitled to Matrix Benefits because his condition is a result of his ingestion of Diet Drugs is erroneous. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to show that they meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred. . . .

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

> . . . [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. The Settlement Agreement unequivocally requires that claimant suffer from at least moderate mitral regurgitation to receive Level II benefits based on the mitral valve. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that his ingestion of Diet Drugs is the cause of his heart-related problems is not pertinent to the issue before the court.

For the foregoing reasons, we conclude that claimant

has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Miller's claim for Matrix Benefits and the related derivative claim submitted by his spouse.